



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,346	03/06/2001	Vladimir L. Makarov	UMIC:039USC1	7290

7590

09/08/2003

David L. Parker
FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, TX 78701

EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
----------	--------------

1637

17

DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/801,346

Applicant(s)

MAKAROV ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 105-125, 127 and 129-152 is/are pending in the application.
- 4a) Of the above claim(s) 107-111 and 116-122 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 136-152 is/are allowed.
- 6) ☒ Claim(s) 105, 106, 123-125, 127, 129-133 and 135 is/are rejected.
- 7) ☒ Claim(s) 112-115 and 134 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action responds the Amendment received on July 7, 2003 (Paper No. 16).

Election/Restrictions

Applicants' request for the reinstatement of claims 107-111 and 116-122 is noted.

Applicants state that 37 C.F.R. 1.142(b) provides for the withdrawal of non-elected invention based on a restriction requirement and not a species requirement. Applicants are advised that 37 C.F.R. 1.142(a) categorizes a species as a distinct and independent invention and the withdrawal of non-elected "invention" is authorized under 37 C.F.R. 1.142(b). Additionally, Applicants cite that the instant case should be governed under 37 C.F.R. 1.146 which is drawn to generic linking claims. The generic claims of the instant application are not linking claims and therefore, Applicants' arguments are moot in view of this finding. Finally, Applicants' attention is drawn to section 809.02(c) of MPEP, wherein the section authorizes the withdrawal of non-elected claims when generic claim is not allowable (see MPEP 809.02(c)(A)).

Therefore, claims 107-111 and 116-122 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 14.

Finally, newly submitted claims 136-152 drawn to the elected species are included in the present prosecution.

Status of Claims

Claims 126 and 128 have been canceled.

Claims 105, 106, 112-115, and 123-125, 127, and 129-152 are under prosecution.

Priority

Applicants are advised that the effective priority of the instant application is March 5, 1998.

Claim Rejections - 35 USC § 112

The rejection of claims 123-125 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on April 9, 2003 is withdrawn in view of the Amendment received on July 7, 2003, amending the claims.

Necessitated by Amendment

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 127, 129, 130, and 131 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants' amendment to claim 105 necessitates the present rejection.

Claim 127 and its dependent claims 127 and 130-131 are indefinite because claim 105 requires that the oligonucleotide adaptor be attached to only one strand of the conditioned DNA fragment. However, claim 127 is drawn to the oligonucleotide adaptor being double stranded, rendering the claim confusing as to how two strands of a double stranded adaptor can be attached a single strand of the DNA fragment.

Claim Rejections – 35 USC § 102

The rejection of claim 127 under 35 U.S.C. 102(e) as being anticipated by Legrain et al. (U.S. Patent No. 6,531,284 B1, issued March 11, 2003, priority February 18, 1998), made in the Office Action mailed on April 9, 2003 is withdrawn in view of the arguments presented in the Amendment received on July 7, 2003.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 105, 106, 123, and 126 under 35 U.S.C. 102(e) as being anticipated by Legrain et al. (U.S. Patent No. 6,531,284 B1, issued March 11, 2003, priority February 18, 1998), made in the Office Action mailed on April 9, 2003 is maintained for the reasons of record. Examiner notes that claim 126 had been canceled by the Applicants.

Applicants' arguments received on July 7, 2003 have been fully considered but they are not found persuasive for the reasons illustrated below.

Applicants argue that the limitation of claim 128 had been introduced to the generic claim 105. Applicants are reminded that claim 128 was drawn to a *double stranded* oligonucleotide adaptor while the presently amended claim 105 is drawn to an oligonucleotide adaptor (including single stranded forms). While the amended limitation recites the phrase, "attaching an oligonucleotide adaptor to only one strand of the conditioned DNA fragment," the disclosure of Upon careful review of Legrain et al., it appears that the reference reasonably discloses this limitation as the adaptors are single stranded adaptors which are ligated to the blunt ends of the

Art Unit: 1637

fragmented DNA which requires that one of the adaptors be ligated to only one strand of the conditioned DNA fragment. Amending the claim to illustrate that the only a single strand of the double stranded oligonucleotide is attached to only one of the strands of the conditioned DNA fragment would overcome this rejection.

Therefore, the invention as claimed is anticipated by Legrain et al.

Claim Rejections - 35 USC § 103

The rejection of claims 128-131 and 134 under 35 U.S.C. 103(a) as being unpatentable over Legrain et al. (U.S. Patent No. 6,531,284 B1, issued March 11, 2003, priority February 18, 1998) in view of Willems (Biotechniques, January 1998, vol. 24, no. 1, pages 26 and 28), made in the Office Action mailed on April 9, 2003 is withdrawn in view of the arguments presented in the Amendment received on July 7, 2003.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 124, 125, 132, 133, and 135 under 35 U.S.C. 103(a) as being unpatentable over Legrain et al. (U.S. Patent No. 6,531,284 B1, issued March 11, 2003, priority February 18, 1998) in view of Willems (Biotechniques, January 1998, vol. 24, no. 1, pages 26 and 28), made in the Office Action mailed on April 9, 2003 is maintained for the reasons of record.

Art Unit: 1637

Applicants' arguments received on July 7, 2003 have been fully considered but they are not found persuasive.

The presented arguments are drawn to the same issues which have been addressed above as the amendment to claim 105 does not distinguish the presently claimed invention from that disclosed by Legrain et al, rendering the claims *prima facie* obvious over the cited references.

Conclusion

Claims 105, 106, 123, 124, 125, 127, and 129-133, and 135 are rejected.

Claims 112-115 and 134 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitation of the base claim and any intervening claims.

Claims 136-152 are allowed as prior art neither teaches or suggests the method of preparing a DNA molecule to, wherein the method involves the generation of DNA fragments which do not have a 3' hydroxyl group by chemical means, wherein the fragments are conditioned to provide a 3' hydroxyl group.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

Art Unit: 1637

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (703)-308-3905. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

9/3/03


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

9/4/03